

HIV, the needlestick and You



Chris Farnitano, MD

Occupational exposure to HIV and
Hepatitis

Noon Conference

Thursday, March 25, 2010

Learning Objectives



- 1. Understand that PEP, while unproven, is likely to be of benefit
- 2. Know the protocol for dealing with occupational exposures

Learning Objectives



- 3. Swallow first, ask questions later:
 - First doses of antivirals are available at all our clinics
- 4. Know protocols for non-occupational PEP

Forms

Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0915-0281, and the expiration date is 5/31/2010. Public reporting burden for this collection of information is estimated to average .12 hours per respondent annually, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to RHA Reports Clearance Officer, 5600 Fishers Lane, Room 10133, Rockville, Maryland, 20857.

ER

HRSA AIDS Education and Training Centers EVENT RECORD

1. Date of Event (mm/dd/yy)

mm	dd	yy
----	----	----

2. Topics (Fill in the circle (•)) to the left of ALL topics covered in the program.)

- Clinical Management/Treatment**
01. Adherence
02. Antiretroviral Treatment
03. Non-ART Treatment
04. Basic Science/Epidemiology
05. Clinical Manifestations of HIV Disease
06. Co-Morbidities
07. HIV Routine Laboratory Tests
08. Hepatitis A, B, C
09. Nutrition
10. Opportunistic Infections
11. Oral Health
12. Pediatric HIV Management/Perinatal Transmission
13. Post-Exposure Prophylaxis, (Occupational & Non-Occup)
14. Resistance
15. Routine Primary Care Screenings
- Health Care Organization and Delivery Issues**
16. Agency Needs Assessment
17. Community Linkages
18. Cultural Competence
19. Education Development/Delivery
20. Grant Issues
21. Health Literacy
22. Health Care Development/Clinical Service Coordination
23. Health Care Organization and Finance
24. HIPAA/Confidentiality
25. Quality Improvement
26. Resource Allocation
27. Technology
- Prevention and Behavior Change**
28. HIV Risk Assessment/Screening
29. Risk Reduction
30. Routine HIV Testing
- Psychosocial Issues**
31. Mental Health
32. Substance Abuse
- Targeted Populations**
33. Adolescent (Ages 13 – 24)
34. Children (Birth – 12)
35. Gay/Lesbian/Bisexual/Transgender
36. Homeless/Unstably Housed
37. Immigrant/Border Populations
38. Incarcerated Individuals
39. People Over 50 Years of Age
40. Racial/Ethnic Minorities
41. Rural Populations
42. Women
43. Other Population (specify) _____

3. Indicate if funds from any of the following initiatives were used to support this event. (Select all that apply)

- 0 American Indian/Alaska Native
0 Minority AIDS Initiative (MAI)
0 Border Health Initiative
0 None of the above

Office Use Only	May 2007	AETC	Sub-site	Program ID
-----------------	----------	------	----------	------------

4. Select all organizations that helped with this event. (Select all that apply)

- 0 None
Other AETCs
0 Delta
0 FL/Caribbean
0 Midwest
0 Mtn. Plains
0 New England
0 NY/NJ
0 Northwest
0 Pacific
0 PA/Mid-Atlantic
0 Southeast
0 TAVOK
0 NE Clinicians'
Consult. Ctr. (NCCC)
0 NE Minority AETC
0 NE Resource Ctr.
0 NE Evaluation Ctr.
- Other Training Centers**
0 Addiction Technology Transfer Center (ATTC)
0 Area Health Ed. Center (AHEC)
0 Prevention Training Center (PTC)
0 Regional Training Center (RTC)
0 TB Training Center
- Other Agencies**
0 AIDS Community-Based Organization
0 College/University/Health Professionals School
0 Faith-Based Organization
0 Community Health Center
0 Historically Black College or University/Hispanic Serving Institution/Tribal College or University
0 Hospital/Hospital-Based Clinic
0 Agencies funded by the Ryan White Program

5. # of Participants

--	--	--	--

6. # PIFs collected

--	--	--	--

7. Length of Session

Total Hours of Event: Fill in hours of event to the nearest quarter hour:
25-1/4 hour, .50-1/2 hour, .75-3/4 hour

Level I	Didactic Presentation		
Level II	Skills Building		
Level III	Clinical Training		
Level IV	Group Clinical Consultation		
Level IV	Individual Clinical Consultation		
Level V	Technical Assistance		

8. Select the following training modalities or technologies that were applied in this event. (Select all that apply)

- 0 Chart/Case Review
0 Clinical Preceptorship/Mini-Residency
0 Computer-based
0 Conference Call/Telephone
0 Lecture/Workshop
0 Role Play/Simulation
0 Self-study
0 Telemedicine

Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0915-0281, and the expiration date is 5/31/2010. Public reporting burden for this collection of information is estimated to average .12 hours per respondent annually, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to RHA Reports Clearance Officer, 5600 Fishers Lane, Room 10133, Rockville, Maryland, 20857.

PIF

HRSA AIDS Education and Training Centers PARTICIPANT INFORMATION FORM

Please completely fill in the circles (•) when answering the questions below.

1. To create your unique ID number, use the month of your birth, day of your birth, and last four digits of your SSN. For example, May 29, 123-345-6789, has the ID number 05296789.

M	M	D	D	#	#	#	#
---	---	---	---	---	---	---	---

Birth Last 4 SSN

Unique ID Number

2. Today's Date (mm/dd/yy)

mm	dd	yy
----	----	----

3. Your Primary Profession/Discipline (Select one)

- 0 Dentist
0 Other Dental Professional
0 Nurse Practitioner
0 Other Advanced Practice Nurse
0 Pharmacist
0 Physician
0 Physician Assistant
0 Clergy/Faith-Based Professional
0 Dietitian/Nutritionist
0 Health Educator
0 Mental Health Professional
0 Public Health Professional
0 Social Worker
0 Substance Abuse Professional
0 Other (specify) _____

4. Your Primary Functional Role (Select one)

- 0 Administrator
0 Agency Board Member
0 Care Provider/Clinician
0 Case Manager
0 Client/Patient Educator
0 Intern/Resident
0 Researcher/Evaluator
0 Student/Graduate Student
0 Teacher/Faculty
0 Other (specify) _____

5. Your Principal Employment Setting (Select one)

- Clinic**
0 Academic Health Center
0 Community Health Center
0 Family Planning
0 HIV Clinic
0 Hospital-Based Clinic
0 Indian Health Services/Tribal
0 Infectious Disease
0 Maternal/Child Health
0 Mental Health
0 Rural Health
0 Sexually Transmitted Disease
0 Substance Abuse
Other Settings
0 College/University
0 Community-Based Organization
0 Correctional Facility
0 HMO/Managed Care Organization
0 Hospital/ER
0 Military/VA
0 Private Practice
0 State/Local Health Department
0 Non-Health
0 Other Primary Care
0 Not Working (skip to item 9)

6. Primary Employment Setting/Zip code

- a. 0 Rural 0 Suburban 0 Urban

--	--	--	--	--	--	--	--

Zip code

7. Is the employment setting a faith-based organization?

- 0 Yes 0 No 0 Don't Know

8. Does the employment setting receive Ryan White Program funding?

- 0 Yes 0 No 0 Don't Know

If you don't know, please write the full name of your employer: _____

9. Are you of Hispanic, Latino/a, or Spanish origin?

- 0 Yes 0 No

10. Your Racial Background (Select all that apply):

- 0 American Indian/Alaska Native
0 Asian
0 Black or African American
0 Native Hawaiian/Other Pacific Islander
0 White

11. Your Gender:

- 0 Female 0 Male 0 Transgender

12. Do you provide services directly to clients/patients?

- 0 Yes 0 No [Stop here. You are done with this form.]

13. Do you provide services directly to HIV-infected clients/patients?

- 0 Yes 0 No [Stop here. You are done with this form.]

14. How many years have you been providing services directly to HIV-infected clients/patients? [Round up to the nearest whole year.]

--	--

15. Estimate the NUMBER of HIV-infected clients/patients to whom you provide direct services in an average MONTH.

- 0 None [Stop here. You are done with this form.]
0 1-9 0 10-9 0 20-49 0 50+

For questions 16-18, estimate the PERCENTAGE of your HIV-infected clients/patients in the past YEAR who were:

16. Racial or Ethnic Minorities

- 0 None 0 1-24% 0 25-49% 0 50-74% 0 ≥75%

17. On Antiretroviral Therapy

- 0 None 0 1-24% 0 25-49% 0 50-74% 0 ≥75%

18. Women

- 0 None 0 1-24% 0 25-49% 0 50-74% 0 ≥75%

For Office Use Only	May 2007	AETC	Sub-site	Program ID	Agency	Ryan White Program 0 Yes 0 No
---------------------	----------	------	----------	------------	--------	-------------------------------------

Case Study:

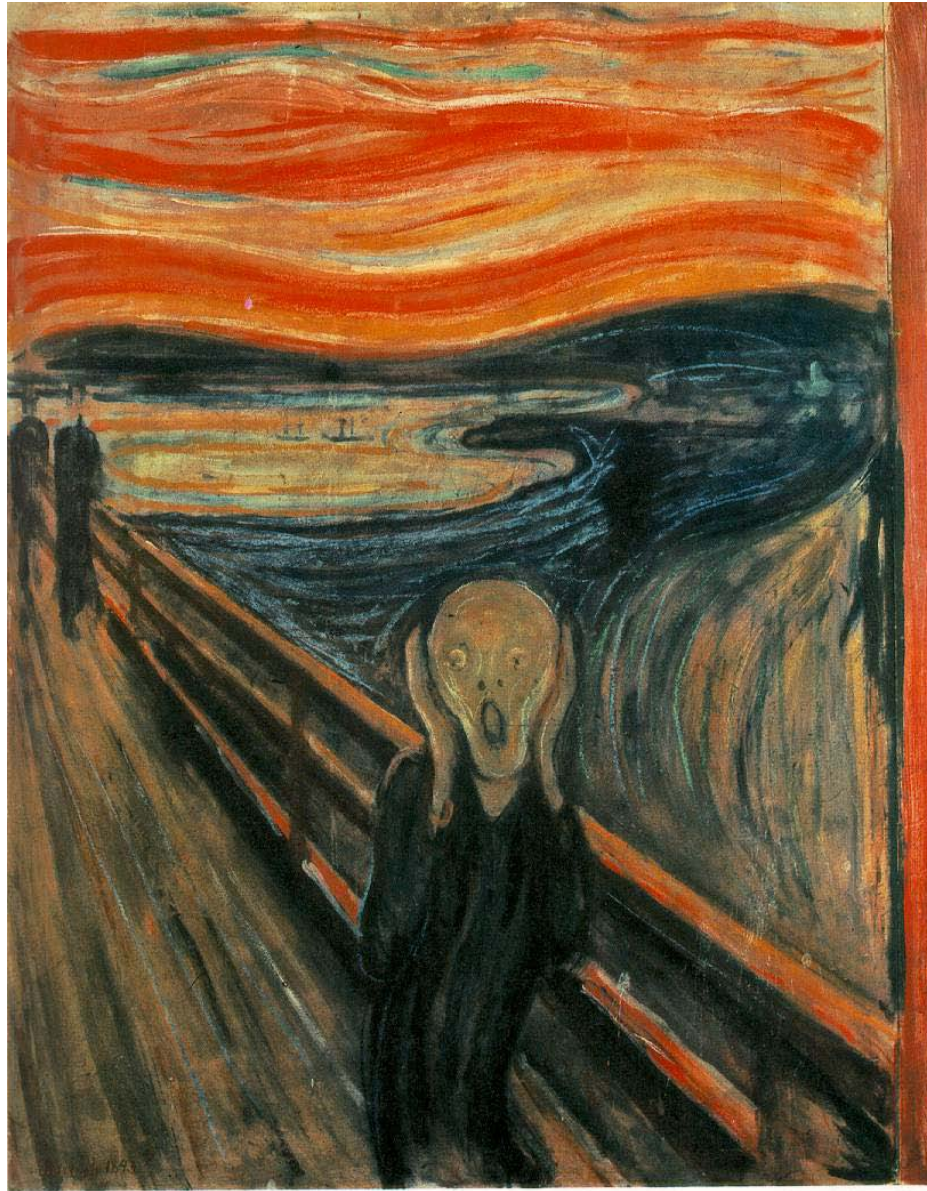


- It's 2AM. You're sewing up a 2nd degree lac on a primiparous HIV positive mom who just delivered a healthy baby boy.
- The lac is deep into the vagina, and it is hard to see where to place your stitches due to bleeding from the laceration.
- Your patient's attention is devoted to the infant, whom she is trying to take a picture of.

- As you place your first stitch, your patient yells "ouch" and jumps.
- You feel a pinprick and inspect your nondominant hand.
- You see blood under the glove of your index finger.



What do you do now?





What do you do now?

- A. Panic
- B. Chop off your finger
- C. Continue caring for the patient and try to forget about the whole thing
- D. Get someone else to take care of the patient, wash the wound, and go to the ED



Occupational infection of health care workers with HIV

- As of December, 2006, in US:
 - 56 documented cases HCW-associated HIV infections
 - 50 were percutaneous source
 - Almost all were hollow bore needles
 - 4 mucous membrane
 - 2 unknown source
- 800,000 est. needlesticks/year in US Hospitals



Retrospective analysis:

- Odds Ratio of acquiring HIV
 - deep injury (IM) 15
 - visible blood on the sharp 6.2
 - source with preterminal AIDS 5.6
 - sharp was in source artery/vein 4.3



Overall transmission rate:

- 0.3% percutaneous exposures
 - 95% confidence interval {CI} = 0.2%-0.5%
- 0.09% bloody splash to mucous membranes
 - 95% CI = 0.006%-0.5%
- <<<0.1% blood splash to skin
- No documented cases of transmission to HCWs from skin exposure



Other body fluids besides blood with potential transmission risk:

- Visibly bloody fluid
- Semen, vaginal secretions, CSF, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, amniotic fluid
- No documented cases of transmission of any of these fluids



What exposures not to treat:

- Feces, nasal secretions, saliva, sputum, sweat, tears, urine, and vomit are not considered potentially infectious unless they are visibly bloody
- Source patient known HIV negative
- Consider treatment if source unknown or source HIV status unknown only if risk factors make source likely to have HIV



Risk of transmission of other agents

- percutaneous exposures:
- Hepatitis B: 2-40%
- Hepatitis C: 1.8%

Immediate Postexposure wound care:

- wash with soap and water
- -antiseptics no proven benefit
- flush eyes with sterile saline or clean water



Postexposure HIV Chemoprophylaxis

- -Standard of Care since 1996



Why?

What's the evidence?



Biologically plausible:



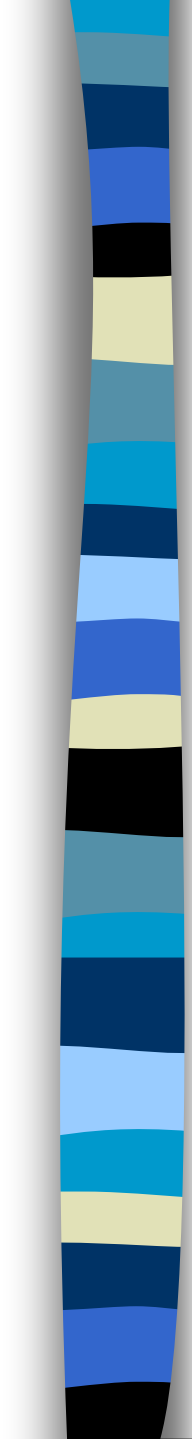
■ -SIV model:

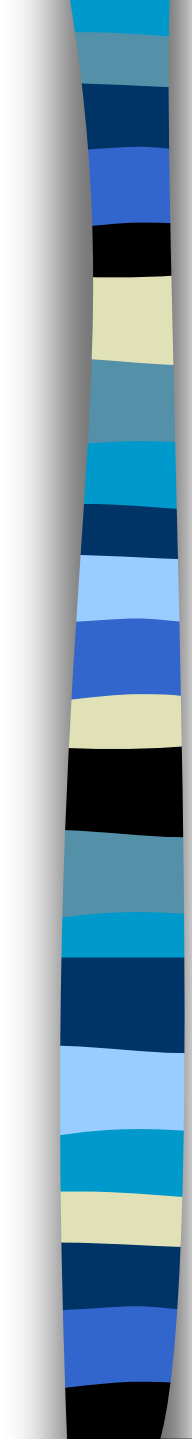
- -Vaginal inoculation

T+24 hrs: virus limited to dendritic cells in mucosa with no evidence of active replication

T+24-48 hrs: virus found in lymph nodes, replicating

T+5 days: free virus detected in bloodstream

- 
- Evidence for aborted infection
T-cell mediated immune responses to viral antigens detectable in humans with high risk exposures who did not become infected

- 
- AZT effective in tissue culture models, SIV monkey models

- Prospective human trials - the perinatal transmission model





ACTG 076

- - AZT reduced perinatal transmission 67%
-treatment benefit not solely explained by reduction in maternal viral titer
- Demonstrated benefit of initiating infant AZT up to 72 hours after birth
(If mom did not receive antivirals, still >50% reduction in transmission if AZT started in infant 0-72 hrs after birth)

Perinatal Transmission rate directly related to use of maternal ART

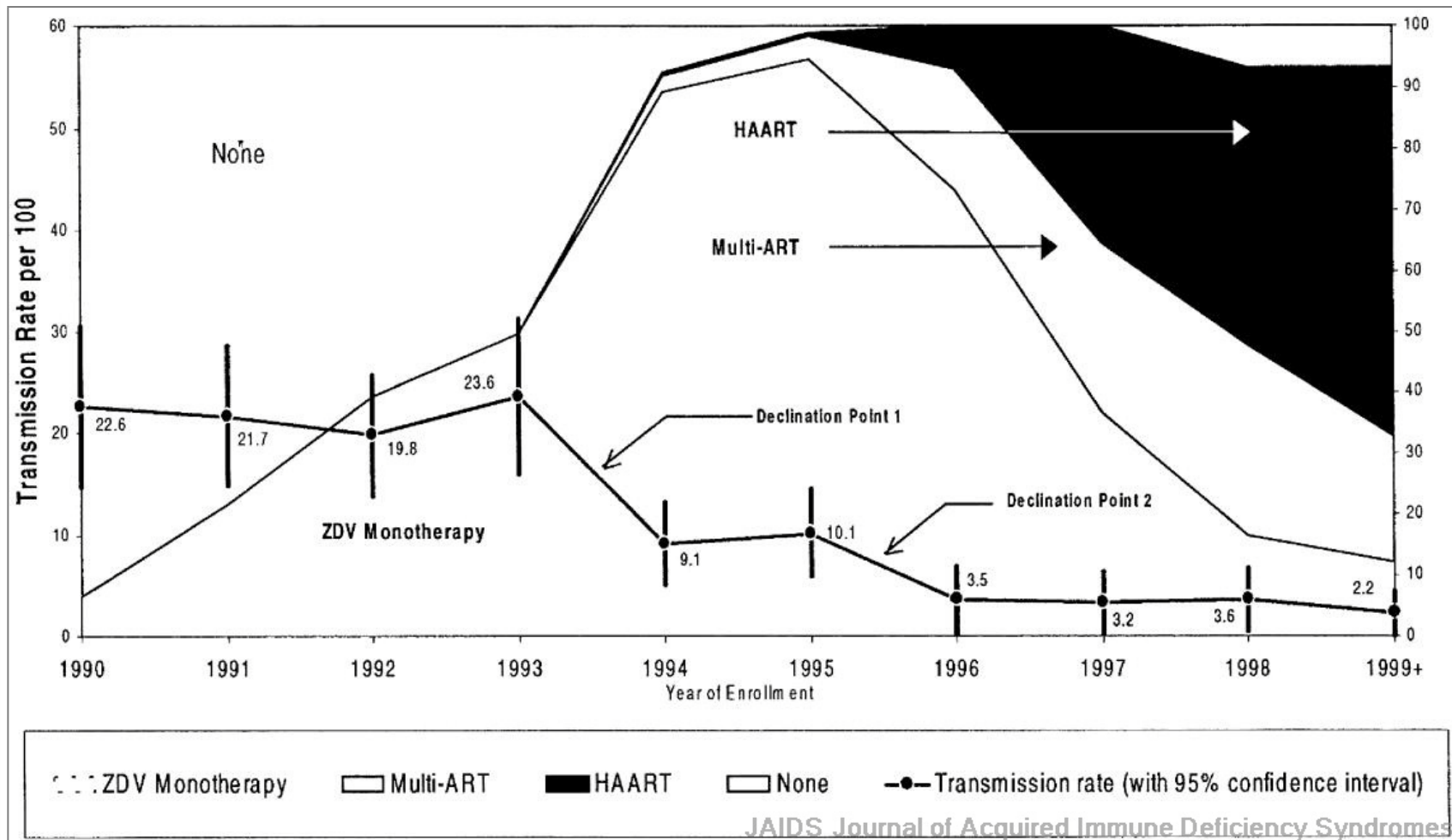


FIG. 1. Trends in mother-to-infant transmission rate and maternal antiretroviral therapy: 1990-1999+ (Women and Infants Transmission Study Group). Rates per 100 (95% confidence interval).



CDC case-control study of occupational HIV exposure

- those receiving AZT 81% less likely (odds ratio = 0.19) to acquire infection, controlled for other variables



CCRMC guidelines mirror Current CDC guidelines

- **U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis**

Department of Health and Human Services
Centers for Disease Control and Prevention

- www.cdc.gov/hiv/treatment.htm
- Last updated September 30, 2005

Start treatment ASAP:

- -Take the first dose, then think about it



Start treatment ASAP:

- You now have 12 hours to ponder the next dose





Treatment initiation after 72 hours?

- still recommended in high risk exposures



Use 2 drugs

- **Standard regimen:**
Truvada (tenofovir + emtricitabine) 1 tab qday
- Alternate regimens:
 - Combivir (Zidovudine/Lamivudine) 1 tab BID
 - Zidovudine (Retrovir; AZT) 300mg BID+ emtricitabine (Emtriva; FTC) 200mg qday
 - Tenofovir (Viread; TDF) 300mg qday + lamivudine (Epivir; 3TC) 300mg qday



Why Truvada?

- **It's better tolerated**

- 73% completed 4 week course of Truvada
- vs. 42% with Combivir



Why Truvada?

- **Side effects of Truvada with PEP:**
 - Diarrhea 37%
 - Bloating, stomach pain 47%
 - Few discontinuations due to side effects
- **Side effects of Combivir with PEP:**
 - Nausea/vomiting >50%
 - Many discontinuations due to side effects
- (Study done with sexual PEP pts.)



Why Truvada?

- Caution: Truvada contraindicated in individuals with impaired renal function



Resistant Virus:

- Use alternate regimens if source patient likely to harbor resistant virus
 - look at medication history: do they have a high viral load (over 1000) despite being on meds?
 - see if patient had an HIV genotype



Resistant Virus:

- 10% of newly diagnosed HIV+ are infected with a resistant strain
 - But only 3.6% have resistance to “nuke” drugs



3 drug regimens recommended:

- In more severe exposures:
 - For example, large-bore hollow needle, deep puncture, visible blood on device, or needle used in patient's artery or vein.
- If high risk source patient:
 - Symptomatic HIV infection, AIDS, acute seroconversion, or known high viral load



3 drug regimens recommended:

- For mucous membrane exposures:
 - Only if both severe exposure and high risk source



3 drug regimen recommended:

Basic regimen plus:

- Lopinavir/ritonavir (Kaletra; LPV/RTV)
200/50 2 tabs BID



ANTIRETROVIRAL AGENTS GENERALLY NOT RECOMMENDED FOR USE AS PEP

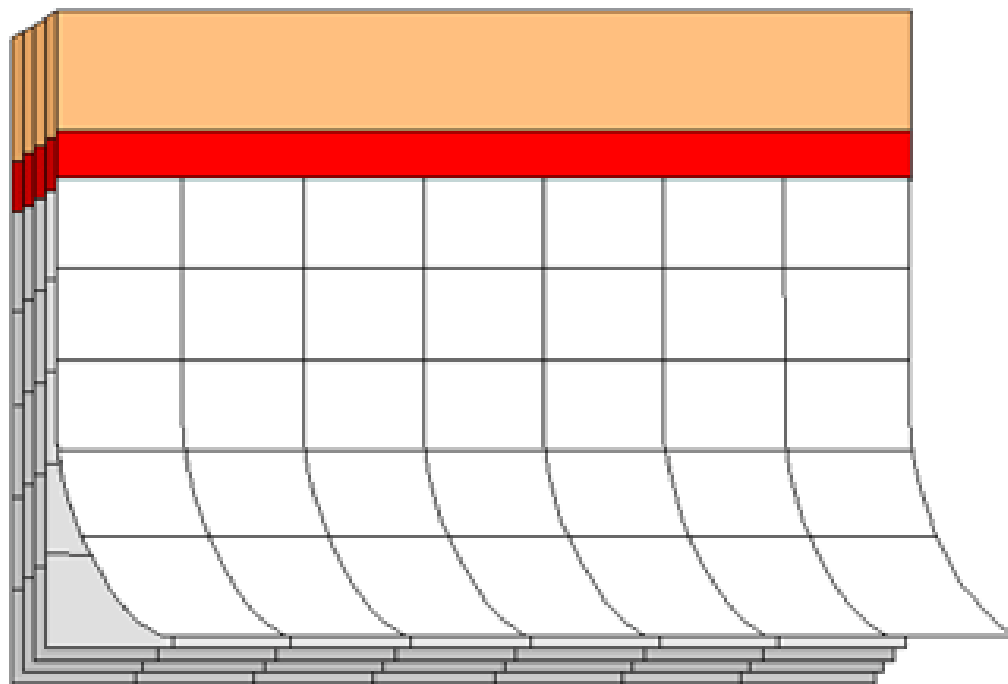
■ Nevirapine (Viramune; NVP)

- Associated with severe hepatotoxicity (including at least one case of liver failure requiring liver transplantation in an exposed person taking PEP)
- Associated with rash (early onset) that can be severe and progress to Stevens-Johnson syndrome

■ Efavirenz (Sustiva, EFV)

- Contraindicated in women who might be pregnant due to risk of birth defects

Treat X 4 weeks





Managing the Exposed Employee

- Find and fill out red needlestick packet
- Do not mention source patient's name or medical record number in patient's paper chart or dictation
- Do record the source patient's name and MR# on the needlestick packet
- Do leave Cathy Ferris a voice mail (370-5079) with source patient's name and MR#



Lab tests -Baseline for employee

- to document prior non-infected status to support/refute worker's comp case
- HepBSab, Hep C ab, LFTs, Urgent HIV
- in order entry under lab order "B/BF EMP



Additional tests if initiating PEP

- HCG, CBC/d, UA, AST, alk phos, CK, t.bili, Cr



Lab tests - on source patient

- urgent HIV, HepBSag, HepC Ab, VDRL
- in order entry under lab order “B/BF SRC



Update immunization status of employee

- Heb B vaccine, HBIG
- Tetanus (give Tdap while you are at it)



Follow up lab monitoring on PEP

- monitor CBC, LFTs after 2weeks on treatment
- check glucose if on PI

Safe Sex

- until 3 month testing results are known





PEP is not Perfect:

- 6 PEP failures well documented since 1992
 - 5/6 hollow needles, 1/6 unknown sharp
 - 5/6 source patients had AIDS, 1/6 had asymptomatic HIV infection but not on meds
 - Employees took 2 drug (2) 3 drug (3) or 4 drug (1) regimens, all initiated in <2 hours after exposure
 - All developed symptoms of acute HIV within 70 days
 - All had documented seroconversion within 100 days



HIV antibody testing:

- -baseline, 6 weeks, 3 months, 6 months
- most seroconvert within 6-12 weeks
- treatment does not delay seroconversion



HIV viral load

- only if symptoms suggestive of acute HIV syndrome (fever, rash, lymphadenopathy, pharyngitis, myalgias)

Side effects of PEP

- 71% HCW had SEs:
 - Nausea (24%)
 - trouble sleeping
 - Fatigue (22%)
 - loss of appetite
 - HA (9%)
 - Emotional upset (13%)
- More SEs with 3 drug regimen
- Anecdotally are higher than in patients taking same meds for established HIV infection





Compliance with PEP

- Compliance with Occupational PEP is poor
When source patient known HIV positive:
63% employees initiate PEP
Of those starting meds:
 - 55% fail to complete 4 weeks of meds
 - 24% failed to complete due to side effects
- 3 drug regimens had lower completion rates



PEP line 1-888-HIV-4911

- Kathy Ferris, RN
 - Infection control coordinator
 - 370-5079
 - beeper 263



Case #2

- 19 y.o. woman presents to the ED
- She states she had intercourse 7 days ago with her boyfriend and the condom broke
- She does not know her boyfriend's HIV status, nor her own
- She asks about medication to prevent HIV from this exposure
- What do you offer her?



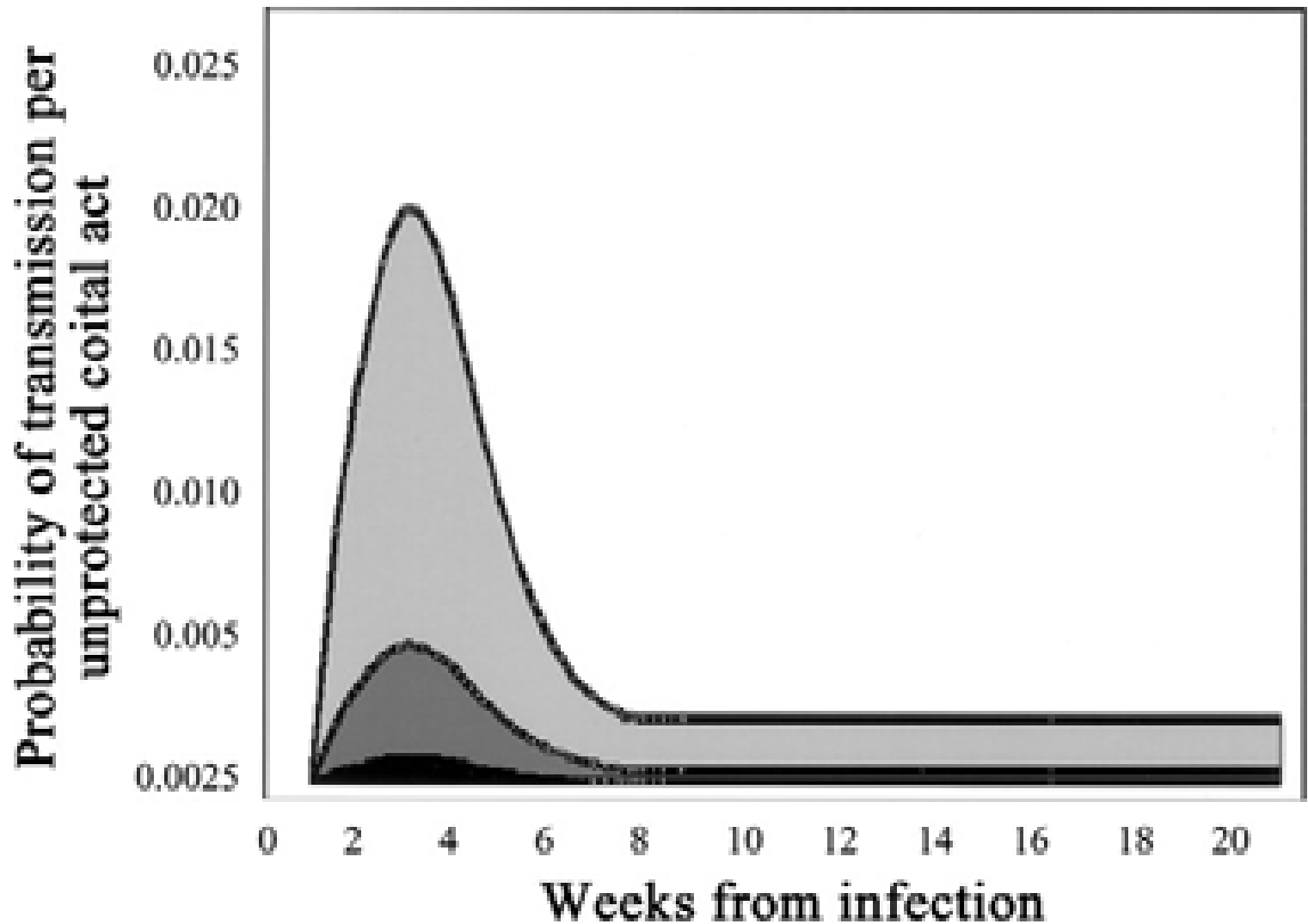
Sexual and other Non-occupational Post-Exposure Prophylaxis

- Risk of one episode of receptive vaginal intercourse is 0.1%, similar to needlestick
- Risk higher with:
 - Receptive anal intercourse
 - Rape and traumatic sex
 - Either partner with genital lesions/ulcers

Estimated Per-Act Risk for Acquisition of HIV, by Exposure Route

Exposure Route	Risk per 10,000 exposures
Blood transfusion	9,000
Needle-sharing injection drug use	67
Receptive anal intercourse	50
Percutaneous needle stick	30
Receptive penile-vaginal intercourse	10
Insertive anal intercourse	6.5
Insertive penile-vaginal intercourse	10
Receptive oral intercourse	1
Insertive oral intercourse	0.5

Infectiousness is directly related to viral load





Sexual Post-Exposure Prophylaxis

- Most common scenarios:
 - Rape evaluation
 - Condom broke
 - One night stand



Sexual Post-Exposure Prophylaxis (S-PEP)

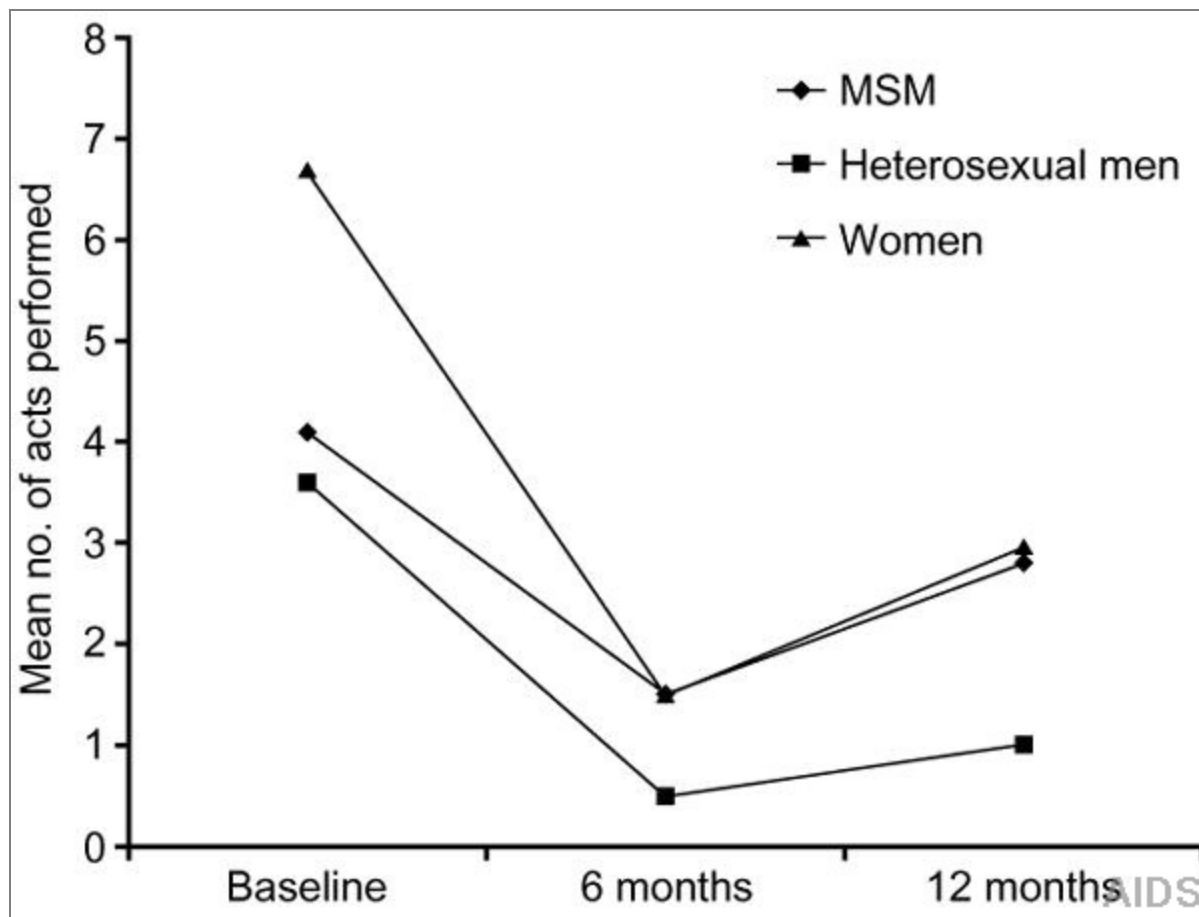
- Effectiveness of S-PEP biologically plausible
- Patients often present later in time than occupational exposures
- Often unclear who source patient is or their risk factors, HIV status
- Opportunity for risk reduction counseling for future exposures



Sexual Post-Exposure Prophylaxis

- Opportunity for risk reduction counseling for future exposures
 - People taking S-PEP reduced instances of unprotected sex by 80% during month of treatment
 - Most patients reported being high on alcohol or drugs or both when had unprotected sex

Use of postexposure prophylaxis against HIV infection following sexual exposure does not lead to increases in high-risk behavior

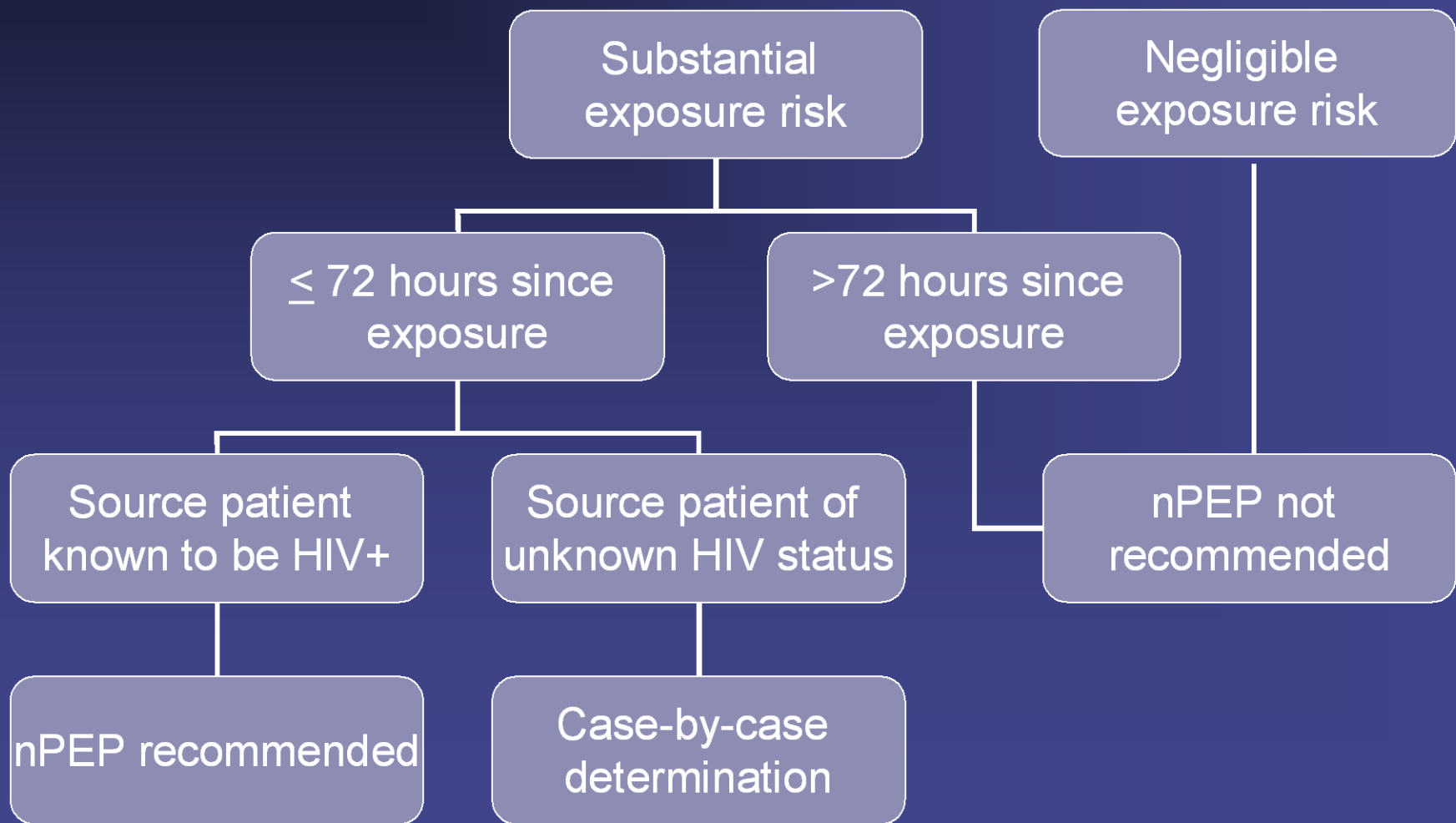




Sexual Post-Exposure Prophylaxis – Recommendations:

- “A 28-day course of HAART is recommended for persons who have had nonoccupational exposure to blood, genital secretions, or other potentially infected body fluids of a persons known to be HIV infected when that exposure represents a **substantial** risk for HIV transmission and when the person seeks care within 72 hours of exposure”

Recommendations for Use of Antiretrovirals for nPEP





3 drugs recommended in S-PEP

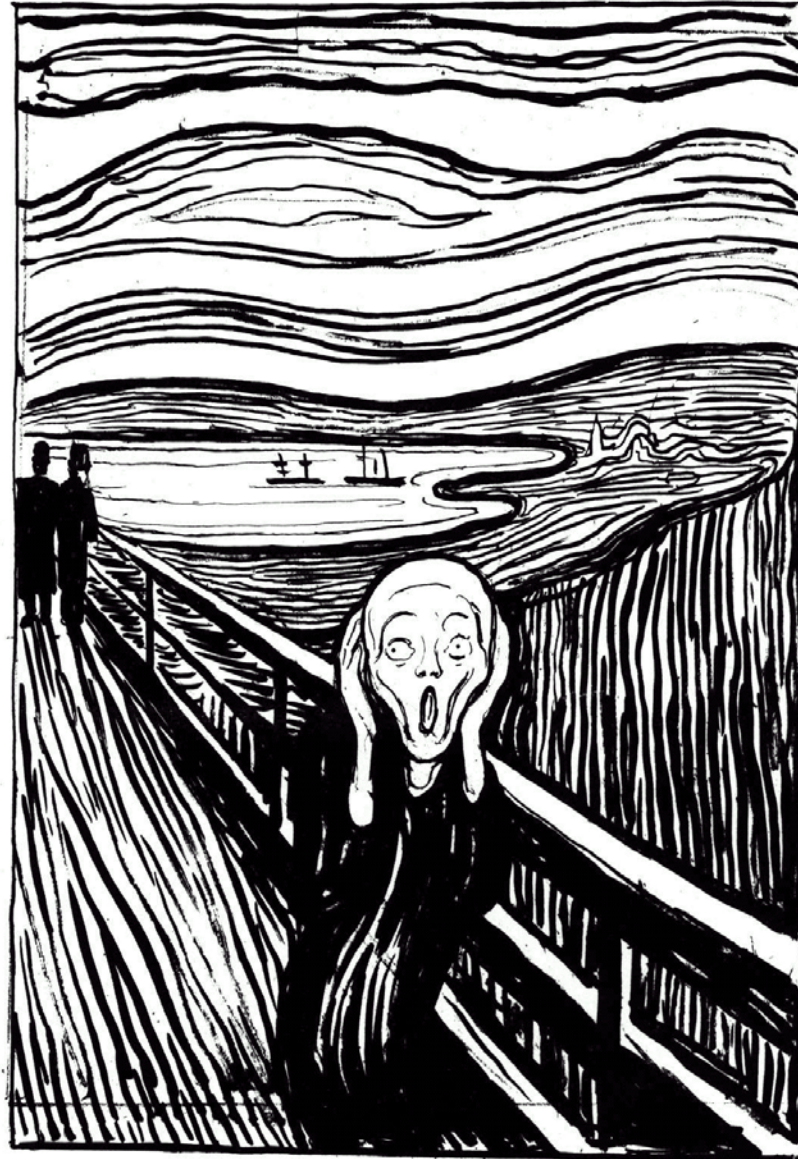
- Higher likelihood patient may already be HIV+
- Delay in presenting to care after exposure increases risk of PEP failure



Semi-related issues

- We miss a lot of opportunities to test:
 - One Urban ER study on offering routine testing to all patients seen in ED:
 - 60% of patients accept testing
 - 1.2% of all patients were HIV+
 - 45% of these had AIDS
 - 11.6% of patients with risk behaviors had HIV
 - 80% had AIDS
 - 77% of those testing positive entered HIV care

Step 1 - Don't Panic!



Step 2 - Get someone else to take care of the patient



Step 3 - Clean the wound



Step 4 - Go to ER or Charge nurse of site to get care per protocol



Prevention:

Universal precautions





FORMS